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Comparison of the primary stability of different tibial baseplate concepts to retain both cruciate ligaments during total knee arthroplasty

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ABSTRACT

Background: A novel tibial baseplate design (Transversal Support Tibial Plateau) as a new treatment concept for bi-cruciate retaining total knee arthroplasty is evaluated for mechanical stability and compared to other tibial baseplate designs.
This concept should provide better primary stability and thus, less subsidence, than implantation of two separate unicondylar tibial baseplates.
Methods: Different baseplates were implanted into synthetic bone specimens (Sawbones® Pacific Research Laboratories, Inc., Washington, USA), all uncemented. Using a standardized experimental setup, subsidence was achieved, enabling comparison of the models regarding primary stability.
Findings: Overall implant subsidence was significantly increased for the two separate unicondylar tibial baseplates versus the new Transversal Support Tibial Plateau concept, which showed comparable levels to a conventional tibial baseplate. Reduced subsidence results in better primary stability.
Interpretation: Linking of two separate baseplates appears to provide increased primary stability in terms of bony fixation, comparable to that of a conventional single tibial baseplate.

1. Introduction

Although the importance of the anterior cruciate ligament (ACL) regarding knee stability, physiologic kinematics, and proprioception is well recognized, to date no bicruciate retaining prosthesis has achieved general acceptance (Nowakowski, 2006).

Non-physiologic knee kinematics are generally observed with the use of ACL-sacrificing implants for total knee arthroplasty (TKA), as documented by numerous in vivo studies (Bolanos et al., 1998; Fuchs et al., 2002; Ishii et al., 1998; Lewandowski et al., 1997; Stiehl et al., 1999, 2000). Dennis et al. (1996) found that knees with posterior cruciate retaining (PCR) prostheses perform similarly to non-replaced knees with (ACL) insufficiency.

One important consideration for the selection of knee prostheses is component fixation. In conventional designs, fixation of the tibial baseplate is most often supported by a central axial stem, either cone-shaped or another geometric form (Nowakowski et al., 2012b). Using such a stem allows retention of the posterior cruciate ligament (PCL). However, retention of the ACL is not possible. During an ACL-retaining procedure, the joint cannot be opened wide enough and/or the tibia cannot be subluxed anteriorly, so a stem of customary length cannot be implanted. In addition, this technique does not allow retention of the ACL insertion in the anterior intercondylar area (Nowakowski et al., 2012b).

As described in our previous study (Nowakowski et al., 2012b), primarily two different approaches have been implemented to retain the ACL during TKA. One solution was the use of a modified PCR prosthesis, in which the recess for the PCL was extended anteriorly (Fig. 1a). Because of the enlarged recess, the connecting bridge between the medial and lateral tibial plates across the anterior tibial plateau is relatively narrow and hence weak. Thus, implant failure can result from the torsion loading in this region (Nowakowski, 2006). In addition, the shorter anchoring elements are less protective against implant loosening. Fixation of such a construct is poorer than that of a traditional plateau, because the central stem is missing (Hamelynck and Stiehl, 2002).

Another solution to retain the ACL has been the implantation of two separate unicondylar knee prostheses. This procedure was reported in 1986 by Goodfellow and O'Connor (Goodfellow and O'Connor, 1986). Precise orientation of two separate unicondylar components can be an intraoperative challenge. In the long term as well, varying subsidence by the separate compartments can lead to implant failure. Even when optimal alignment of two separate unicondylar tibial baseplates (2× Uni) is attained intraoperatively, different implant subsidence medially and laterally can lead to asymmetry of the joint surface levels

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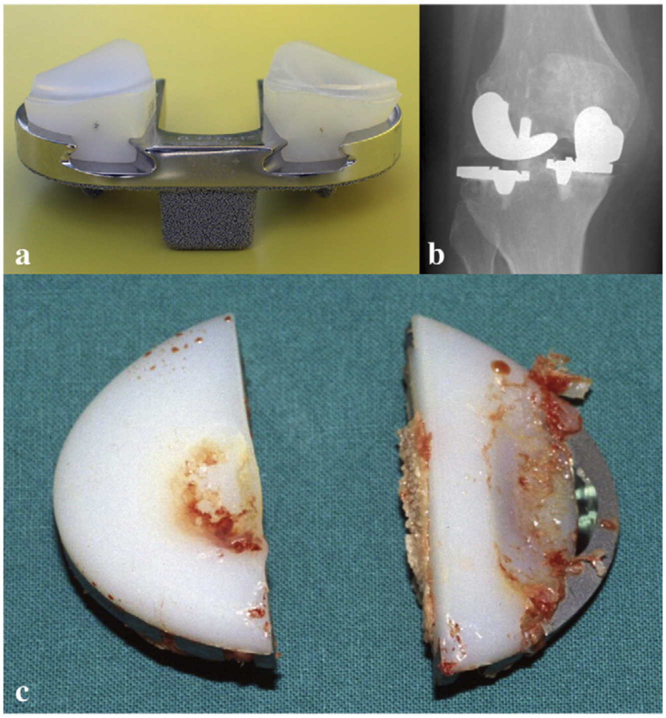

Fig. 1. Current approaches to retain both cruciate ligaments in total knee arthroplasty (Nowakowski et al., 2012b): a) LCS® bicruciate retaining prosthesis as an example of a PCR prosthesis derivative: fixation is not as good as in traditional PCR prostheses because of the lack of a central stem. Only short anchoring wings can be used. b) Radiograph of a knee treated with 2 unicondylar knee prostheses: even when optimal alignment of both plateaus is attained intraoperatively, implant subsidence can lead to asymmetry of the joint surface levels and malalignment of the components. Such unfavorable loading and abrasion can lead to increased PE wear. c) Explant from Fig. 1b: the medial PE inlay was completely eroded after just 6 years and revision arthroplasty was required (Nowakowski, 2006). Reprinted by courtesy of the Medical Literary Publication Society (Medizinisch Literarische Verlagsgesellschaft mbH), Uelzen, Germany.

Fig. 2. The transversal support tibial plateau consists of two joint surfaces, reinforced beneath the joint line by two joint surface supports and linked by a single transversal support (TS).

and malalignment of the components (Fig. 1b). As a result unfavorable loading can lead to increased wear and excessive erosion (Fig. 1c).

Despite this, the implantation of two separate unicondylar knee prostheses has increased in popularity (Banks et al., 2005; Confalonieri et al., 2009; Fuchs et al., 2005). These considerations prompted us to develop the transversal support tibial plateau (TSTP) concept (Nowakowski, 2002, 2006). Essentially, the TSTP consists of two individual joint surfaces (JS) reinforced beneath the joint line by joint surface supports (JSS), and linked by a single transversal support (TS) (Fig. 2).

This configuration should provide good bony fixation and secure long-term alignment of the individual joint surfaces (Nowakowski, 2006).

In a previous study (Nowakowski et al., 2012b), four different designs of this concept were implemented and compared. We used a standardized experimental setup to assess primary stability of the tibial baseplates. The current study compares the preferred TSTP design from this previous testing with 2× Uni and conventional (TBPstd) tibial baseplates of total knee prostheses.

The primary hypothesis of this study was that the TSTP provides better primary stability than the 2× Uni. The second hypothesis was that the TSTP can achieve similar primary stability as the TBPstd.

2. Methods

The experimental setup used to assess the primary stability of tibial baseplates was published in our previous study (Nowakowski et al., 2012b). In the current study, in addition to the selected transversal support tibial plateau (TSTP) model, we examined a model with two separate unicondylar tibial baseplates (2× Uni), and one with a conventional tibial baseplate (TBPstd). These were implanted into the synthetic bone specimens, all without cement.

For the TBPstd model, the e.motion® design (size F7, Aesculap AG, Tuttlingen, Germany) was used, and for the 2× Uni model, the univation® design (Aesculap AG, Tuttlingen, Germany) medial and lateral devices were selected, in corresponding sizes. The tibial baseplates of the TSTP model were developed according to the size F7 of the TBPstd model. Axial load was transmitted over a conventional femoral component (e.motion® size F7, Aesculap AG, Tuttlingen, Germany) and corresponding inlays (flat prepared to the tibial side, 20 mm thickness to minimize shearing-forces).

Implantations were performed with the original instruments according to the surgical instructions provided by the manufacturer. In this way, load transfer within the implant-to-bone interface was somewhat comparable to that of the early postoperative situation after total knee arthroplasty. With the TSTP model, a customized aiming device was used for insertion of the TS. In all models, load was transferred at all contact points between the implant and cancellous bone.

The experimental setup (Fig. 3) detailed in our previous study (Nowakowski et al., 2012b) is comprised of the following specifications. Large left fourth generation composite tibial Sawbones® specimens with a specified cancellous bone density of 12.5 pcf were used. They were prepared by grinding the cortex in the tibial plateau resection plane area.

Cyclical load application was performed on the components according to the ASTM F1800-07 (2007) and ISO 14879-1 (2000) standards. Both of these standards define testing for the fatigue of metallic tibial trays used in knee joint replacements. For this purpose, the tibial trays to be investigated were mounted laterally. Cyclic load was applied to the unsupported condyle through an ultra-high molecular weight polyethylene (PE-UHMW) spacer. The load was defined as a sinusoidal dynamic loading waveform or, if not sinusoidal, a smooth waveform with no overshoots. The ratio from the maximum to minimum loads was given as an R value of 10.

Thus, for this testing setup, a corresponding load ratio F_{min}/F_{max} of 1:10 was used. Also according to these standards, a one second cycle duration of the sinusoidal load was applied using a four column dynamic test machine (Dyna-Mess, Stolberg, Germany). The axial force was distributed in a proportion of 60/40% between medial and lateral,

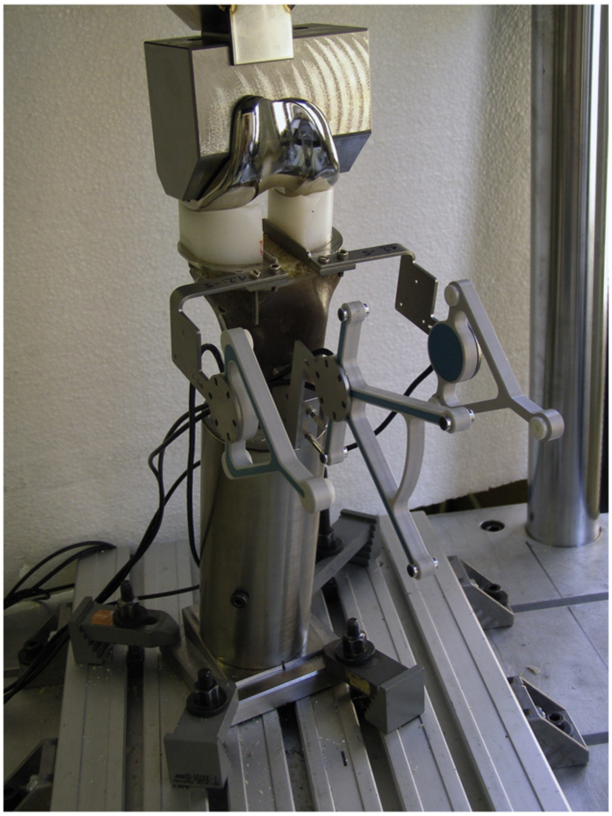

Fig. 3. Experimental set-up: sinusoidal load application with a four-columned dynamic test machine (Dyna-Mess, Stolberg, Germany). A special control device was used to distribute axial force over a conventional femoral component (e.motion® size F7, Aesculap AG, Tuttlingen, Germany) and the fitted inlays. To measure the relative motion between the JS and the bone, an ultrasound-based 3D motion analysis system (CMS20BI, Zebris, Isny, Germany) was used.

as suggested by Zhao et al. (2007). Point transmission of force was deflected in a proportion of 70/30% towards posterior, as suggested by de Jong et al. (2010). The initial load level measured F_{min} 90 N and F_{max} 900 N, and the load was incrementally increased in ten steps to a maximal load of 360 N and 3600 N, when tolerated. In cases where the testing machine reached its built-in safety limit (because of massive subsidence and/or tilting), the last measurement level prior to override was taken for analysis.

To record subsidence, an ultrasound-based 3D motion analysis system (CMS20BI, Zebris, Isny, Germany) was used to measure the relative motion between the implant models and the bone at defined moving points (MP, Fig. 4). Positioning of the MPs on the distal implant edges was selected because these were the locations where the largest subsidence distances could be identified, and also because in these areas, the measurement uncertainty using the Zebris system (resolution according to the manufacturer between 0.1 and 0.01 mm) exerted the least influence.

Load application was performed for each model in three series (each model was implanted into three separate bone samples). Transmission of force was carried out with 2500 cycles per load level, thus a total of 25,000 cycles. To reduce the enormous amount of data, recordings were taken at each 50th cycle for 2 s with a sample rate of 25 Hz. The 2 second duration was defined to ensure at least 1 complete sinus cycle with a total of 25 measured values.

A multivariate analysis of variance model, ANOVA, was fit to the data with the variables "model" and moving point ("MP") as well as the corresponding interaction term (log(subsidence + 1) − model + MP + model:MP). The response variable, i.e. the subsidence, was analyzed on the logarithmic scale, $\log(x + 1)$. This transformation was selected to comply with the model assumptions (normal distributed residuals)

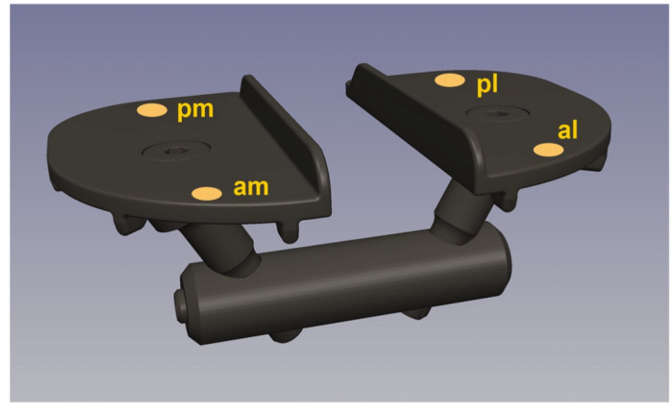

Fig. 4. Changes in subsidence were measured on the basis of four defined moving points (MP) (anterior medial (am), anterior lateral (al), posterior medial (pm), posterior lateral (pl)).

and to allow for values of zero. Model assumptions were visually inspected by means of quantile–quantile plots. Contrasts were defined a priori and specified manually (TSTP vs. TBPstd and TSTP vs. 2× Uni; medial vs. lateral and anterior vs. posterior). All tests were performed with a significance level of 0.05. Calculations were carried out using the statistical software R (R Development Core Team, 2009), version 2.10.

3. Results

For each of the three models, three measurements of subsidence were taken at each of the four moving points (MP), yielding a total of 36 measurements.

As reported previously (Nowakowski et al., 2012b), subsidence tended to increase for all three models with increasing load levels, and the largest subsidence for each model was measured at the highest load level attained. However, in contrast to the previously published results, in the current study, not all models attained the highest load level (F_{min} 360 N/F_{max} 3600 N). For the 2× Uni model, massive subsidence and medial tilting resulted twice in stoppage when the testing machine reached its built-in safety override (Fig. 5). This occurred for the first time at load level 9, and the second time at load level 10. Thus, the average for each of the three test series for the model 2× Uni was calculated using the last documented values as endpoints. These were the values recorded one level prior to failure,

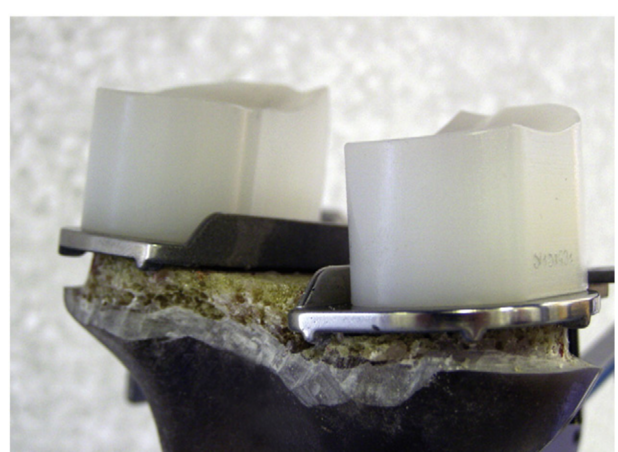

Fig. 5. Massive subsidence and tilting led to successive malalignment after loading of the 2× Uni model, resulting in automatic stoppage of the testing machine due to safety override settings.

i.e. once at load level 8 (F_{min} 300 N/F_{max} 3000 N) and once at load level 9 (F_{min} 330 N/F_{max} 3300 N).

The largest measured average of subsidence levels for each of the three test series was 7.8 mm (SD 2.6 mm) for the posterior medial MP of 2× Uni (Fig. 6a). Although further analysis of the individual joint surfaces (JS) was a theoretical option at this point, it was not performed since similar calculations could not be carried out on the single piece TBPstd design. Subsidence of the joint surfaces (JS) was apparent on the combined anterior and posterior MP measurements (Fig. 6b). With 5.3 mm (SD 3.2 mm) medially, JS subsidence was significantly increased for the 2× Uni design concept compared to the other two models ($P < 0.001$; Table 1). In contrast, the lateral subsidence of the 2× Uni model tended to be less than that of the TSTP and TBPstd models. This is also reflected by the estimates of the multivariate statistical model (Table 1). The multivariate analysis revealed a statistically significant interaction between the model and the position (MP) ($F_{4,27} = 23.596$, $P < 0.001$) which means that the position-specific subsidence varies between the models (Table 2). The difference between the medial and lateral subsidence varies between the models. A significantly higher medial compared to lateral subsidence was found in Uni in comparison with TSTP (Table 1, $P < 0.001$), which is not found between the TBPstd and TSTP models. The subsidence was generally higher at posterior than at anterior ($P < 0.001$) but the difference did not vary significantly between the models.

Total implant subsidence was estimated by calculating the averages over all four MPs (anterior medial, anterior lateral, posterior medial, and posterior lateral) (Fig. 7). Whereas subsidence of the TSTP design, with 1.5 mm (SD 0.9 mm), was similar ($P = 0.63$; Table 1) to the measurements of the TBPstd design, with 1.6 mm (SD 0.9 mm). The 2× Uni model had significantly ($P = 0.01$in the multivariate analysis; Table 1) more subsidence, with 2.9 mm (SD 3.3 mm).

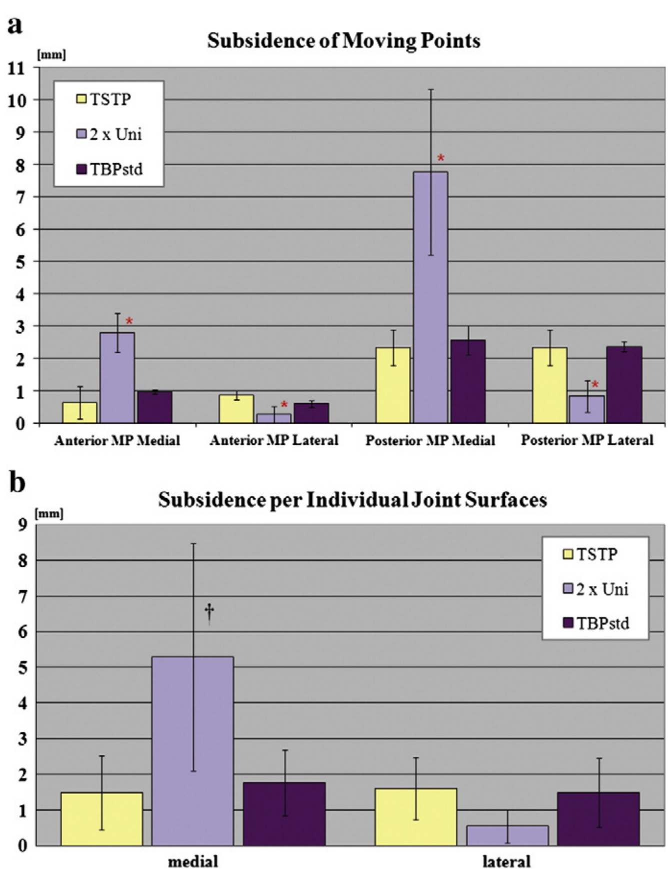

Fig. 6. Summary of average values per model: a) All endpoints of subsidence after the maximum reached load levels (Level 10 for all measurements of TSTP and TBPstd), * Model 2× Uni was calculated for levels 8, 9, and 10, respectively, after twice surpassing the safety override conditions of the machine, b) Depiction of the summarized averages from anterior and posterior MPs of each JS, † Medial compared to lateral subsidence was significantly higher in 2× Uni as compared to TSTP (see multivariate statistical analysis in Table 1, $P < 0.001$).

Table 1
Estimated additive effect on the log scale together with the 95% confidence interval (95% CI). The first two rows refer to the difference between the models according to the defined contrasts. The next two rows refer to the main effect of MP. And the remaining rows refer to the interaction between model and MP. E.g. the medial subsidence compared to the lateral is significantly lower in TSTP in comparison to 2× Uni. The intercept corresponds to the estimated mean subsidence on the logarithmic scale.

	Estimate	95% CI	*P*-value
(Intercept)	0.95	0.88 to 1.01	<0.001
TSTP vs. TBPstd	−0.02	−0.10 to 0.06	0.63
TSTP vs. 2× Uni	−0.10	−0.18 to 0.02	0.02
medial–lateral	0.46	0.33 to 0.59	<0.001
anterior–posterior	−0.64	−0.77 to −0.50	<0.001
TSTP vs. 2× Uni: anterior–posterior	−0.03	−0.19 to 0.13	0.68
TSTP vs. TBPstd: anterior–posterior	0.01	−0.15 to 0.17	0.92
TSTP vs. 2× Uni: medial–lateral	−0.70	−0.87 to −0.54	<0.001
TSTP vs. TBPstd: medial–lateral	−0.10	−0.27 to 0.06	0.19

4. Discussion

Retention of the ACL during TKA should lead to increased joint stability, physiologic motion of the joint with improved gait pattern, and improved proprioception and balance (Nowakowski et al., 2012b). Implantation of bicruciate retaining designs is understood to be technically difficult; therefore, respect of “natural gap kinematics” is probably important in preventing cruciate ligament overload (Nowakowski et al., 2012a). On the other hand, advanced arthritic changes may lead to ACL insufficiency. According to Lee et al. (2005), some 60% of ACLs may be usable, even when they are not completely normal (Nowakowski et al., 2012b).

Confalonieri et al. (2009) found that ACL retention through implantation of two separate unicondylar knee prostheses yielded shorter hospitalization as well as better postoperative function compared to conventional TKA. In comparison to normal unilateral insertion of unicondylar knee prostheses, Fuchs et al (Fuchs et al., 2005) found the same good functional outcomes for implantation of two separate unicondylar knee prostheses.

However, according to our hypothesis, the 2× Uni implantation concept would exhibit disadvantages in terms of primary stability.

The current study compared primary stability attained by the selected TSTP model with that of a typical tibial baseplate (TBSstd) and that of two unicondylar knee prostheses (2x× Uni), using the experimental set-up detailed in our previous study (Nowakowski et al., 2012b).

After loading specially prepared Sawbones® specimens with a sinusoidal oscillating load transmission of 25,000 cycles over 10 increasing load levels, this standardized test assembly achieved implant subsidence. This, in turn, enabled comparison of the various implants, especially regarding primary stability and thus, bony fixation (Nowakowski et al., 2012b).

As described in our previous study (Nowakowski et al., 2012b) using this test set-up to produce subsidence, the margin of difference between

Table 2
ANOVA table for multivariate statistical model containing “Model”, moving point (“MP”) and the interaction term (“Model:MP”). The interaction is highly significant which means that the position-specific subsidence varies between the models.

	Df	Sum sq	Mean sq	F value	Pr(>F)
Model	2	0.27	0.13	3.66	0.0392
MP	2	5.54	2.77	75.13	<0.001
Model:MP	4	3.48	0.87	23.60	<0.001
Residuals	27	1.00	0.04		

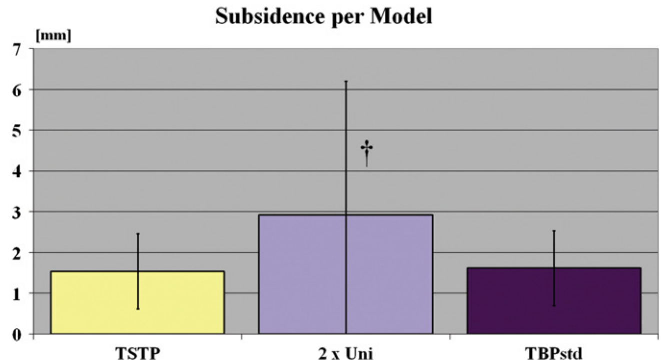

Fig. 7. Total subsidence per implant. † In the multivariate model (Table 1) variant 2× Uni showed significantly more subsidence than TSTP ($P = 0.01$). However the subsidence is highly position specific.

the anterior and posterior MPs versus that between the medial and lateral MPs was significantly larger, as was the direct contrast between the anterior and posterior MPs.

The current results indicate that the independent joint surfaces of the 2× Uni developed increased tilt and subsidence than the interconnected TSTP implant and the standard TBPstd single baseplate design. Thus, it appears that fixation and primary stability of the 2× Uni are not as good as that of the typical TBPstd prosthesis with a central stem. In comparison to the TSTP model as well, the bilateral unicondylar prostheses showed significantly greater subsidence values.

Regarding subsidence, the current study identified no significant differences between the TSTP concept model and the typical TKA baseplate design. Thus, the evidence here appears to confirm the hypothesis that the TSTP concept is comparable with conventional prostheses regarding subsidence and primary stability.

As described previously (Nowakowski et al., 2012b), the major limitation of this study is the use of synthetic instead of cadaveric bone. However, the use of synthetic bone does offer advantages regarding reproducibility and comparability of the models. It does not account for individual differences in bone quality within the medial and lateral compartments of the joint. For this reason, using this experimental setup with identical bone quality on each side and force distributions of 60/40% medial to lateral and 70/30% posterior to anterior, there was markedly increased posteromedial subsidence, especially for the 2× Uni model. Even if the force and distribution were extreme in comparison to in vivo measurements (D'Lima et al., 2006; Wasielewski et al., 2005; Wretenberg et al., 2002), however, it appears that the 2× Uni concept cannot equalize and compensate for eccentric loading.

Another limitation of this study was that it considered only a non-cemented implantation technique. Cemented implants might yield different results.

In addition, loading of the implants in this experimental setup was somewhat unrealistic, since the load transmission is concentrated in one vector and on one point. This setup did not consider rollback or rotational knee-movement according to the ASTM standard. It also did not include the additional rotational moments described by Heinlein et al. (Heinlein et al., 2009). In vivo measured moments depend on the implemented design, especially regarding fixed bearing and congruency of the inserts, and they are not standardized.

Overall implant subsidence was significantly greater for the 2× Uni model versus TSTP and TBPstd models, with the latter two showing comparable levels. Thus, linking of the separate JS appears to provide increased primary stability comparable to that offered by a conventional single tibial baseplate. On the other hand, implantation of the TS does require a small additional operative step. This can be performed through a medial or lateral approach depending on the distance interval of the TS to the joint line (Nowakowski et al., 2010).

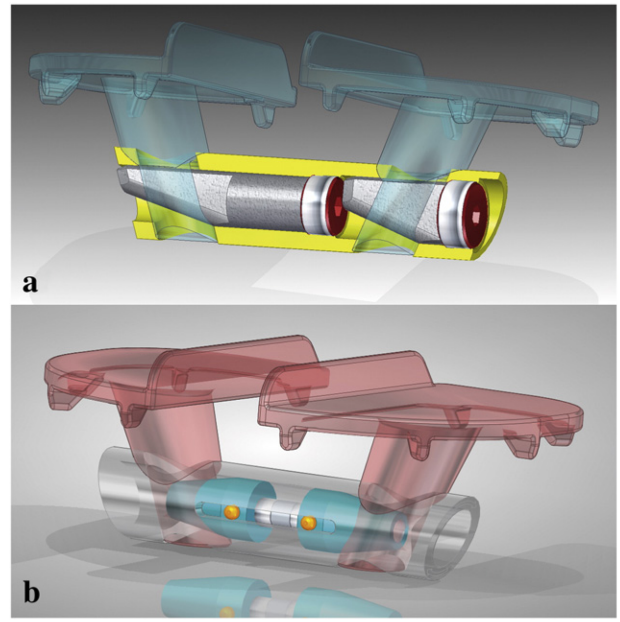

Fig. 8. Approaches to fixation of a fitted connection of the two JS to the TS. The locking mechanism may press-fit the JS to the TS, resulting in increased pressure on the underlying bone. a) Fixation by successive application of wedges, which first pull the JS into the final position and then arrest further movement, b) Fixation with cones, which are initially positioned internally during implantation, and then pushed apart over a thread.

Depending on the configuration and the fixation of the modular elements of the TSTP design to the JS, it is possible that additional pressure might be applied to the remaining bone stock (Fig. 8). Whether primary stability would increase with the addition of "press fit," and whether this would have positive osseointegration effects are questions to be addressed in further studies.

One additional study (Nowakowski et al., 2013) suggests that it may be advantageous to reduce the axial distance between the two individual joint surfaces (JS) and the single transversal support (TS) to a distance of between 15 and 25 mm by shortening the joint surface supports (JSS). With this shortened construction, there is no need for modularity between the JS and JSS, since a unified joint surface implantation would be completely possible. In this case, the risk of implant failure due to the modular relationship can be minimized. However the definitive design must pass testing according to current standards.

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